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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,778	01/24/2002	Thorsten Siess	IMPEL .57972	7976

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/890,778

Applicant(s)

SIESS ET AL.

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/24/2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 8-13, drawn to a device for intravascular cardiac valve surgery.

Group II, claim(s) 14-17, drawn to a device for intravascular cardiac valve surgery including a cardiac valve prosthesis and a stent.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: micro axial pumps and dilating devices are known in the art and the claimed inventions involve two different procedures, breaking up a stenosis and installing a stent-valve prosthesis.

3. During a telephone conversation with Gunther Hanke on March 20, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 8-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Drawings*

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "24" has been used to designate both a section of blood vessel and the hose-shaped wall. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "25" has been used to designate both the vascular valve and the valve leaflets. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,753,221 to Kensey et al.

Regarding claim 8, Kensey discloses a microaxial pump fastened to a catheter (proximal end of catheter tube 450) and having a tubular pump portion (pump means 42 and distal end of catheter tube 50) and a dilating device (balloon 52) surrounding the pump portion.

Regarding claim 9, Kensey discloses that the pump portion comprises a pump ring (support 70) and a tubular cannula (distal end of catheter 50).

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. '221 in view of U.S. Patent No. 4,777,951 to Cribier et al.

Kensey teaches the claimed invention except for the use of a high-pressure balloon seated on a rigid annular support. Cribier teaches a balloon for use in valvuloplasty (Column 2 lines 23-27) that utilizes a rigid support in order to provide a catheter that can be grasped and thrust by the surgeon without unwanted distortion of the catheter (Column 4 lines 20-46). Cribier also teaches that these balloons are inflated to a pressure of at least one bar (Column 8 lines 56-59) to break up stenosis in a valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon of Kensey (balloon 52) with the rigid support, as taught by Cribier, in order to allow the surgeon to maneuver the catheter without distorting the catheter and to provide the balloon of Kensey with high-pressure capabilities, as taught by Cribier, in order to break up a stenosis in the valve.

*Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to balloon catheters and pumps:

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U.S. Patent No. 4,796,629 to Grayzel

U.S. Patent No. 5,855,597 to Jayaraman

U.S. Patent No. 4,919,647 to Nash

U.S. Patent No. 5,921,913 to Siess

U.S. Patent No. 5,209,728 to Kraus et al.

U.S. Patent No. 6,083,260 to Aboul-Hosn

U.S. Patent No. 5,221,258 to Shturman

U.S. Patent No. 6,245,102 to Jayarman

U.S. Patent No. 5,376,114 to Jarvik

U.S. Patent No. 6,248,091 to Voelker

U.S. Patent No. 5,820,542 to Dobak, III et al.

U.S. Patent No. 6,533,716 to Schmitz-Rode et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

*JRB*  
jrb

March 24, 2003

*[Signature]*  
KEVIN T. TRUONG  
PRIMARY EXAMINER

3/24/03